

REMARKS

In the Office Action, the disclosure is objected to; the Abstract is objected to; claims 1-10 and 12-20 are rejected under the judicially created doctrine of obviousness-type double patenting; claims 1-10 and 12-20 are rejected under 35 U.S.C. § 112 second paragraph; and claims 1-10 and 12-20 are rejected under 35 U.S.C. § 103. Applicants believe that the rejections have been overcome in view of the amendments and for the reasons as set forth below.

At the outset, the Patent Office has objected to the disclosure and the Abstract as previously discussed. In response, Applicants have amended the disclosure and have also amended the Abstract so as to be provided on a separate sheet. Applicants believe that they have been responsive to the Patent Office's comments (Office Action, pages 2-3) and thus respectfully request that the objections to the disclosure and Abstract be withdrawn. Moreover, Applicants have amended the disclosure to include a priority statement as further commented by the Patent Office on page 2 of the Office Action.

In the Office Action, claims 1-10 and 12-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-35 of U.S. Patent No. 6,777,391. As presently pending, Applicants believe that this rejection is improper with respect to claims 1-10 and 12-20 and thus respectfully request that this rejection be withdrawn.

In the Office Action, claims 1-10 and 12-20 are rejected under 35 U.S.C. § 112 second paragraph. In response, Applicants have amended the claims to address the alleged issues regarding the claim terms "tryptophan rich," "about," "substantially," and "an effective amount." Thus, the rejections with respect to same should be withdrawn.

Further Applicants consider that the claim terms, "lipid source, a carbohydrate source and a protein source," are commonly used words as generally understood by the skilled artisan and that describe the origin of such a compound, either by containing the compound in a release form or after degradation processes, such as acidic degradation of proteins to free amino acids. Thus, Applicants believe that the claim terms, "lipid source, a carbohydrate source and a protein source," as fully supported in the specification are clear and definite in meaning and scope to one skilled in the art. Based on at least these reasons, Applicants believe that the presently pending

claims satisfy the requirements pursuant to 35 U.S.C. § 112 second paragraph. Accordingly, Applicants respectfully request that this rejection be withdrawn.

In the Office Action, claims 1-10 and 12-20 are rejected under 35 U.S.C. § 103 as allegedly unpatentable over XP-002158762. Of the pending claims at issue, claims 1, 10, 12, 13 and 20 are the sole independent claims. Claim 1 recites a composition for an infant formula. The composition includes whey protein wherein the whey protein is acid or sweet whey protein from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; histidine; milk protein that has a level of 5% or more of amino acids as tryptophan, free tryptophan or a mixture thereof. Claim 10 recites a method of producing an infant formula. The method includes blending whey protein that does not contain caseino-glyco-macropeptide, and casein protein together with free arginine; free histidine; and milk protein that has a level of 5% or more of amino acids as tryptophan, free tryptophan or a mixture thereof and homogenizing the blended mixture.

Claim 12 recites a method of treating malnutrition. The method includes administering a composition that contains whey protein, wherein the whey protein is acid or sweet whey protein from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; free histidine; milk protein that has a level of 5% or more of amino acids as tryptophan, free tryptophan or a mixture thereof. Claim 13 recites an infant formula that includes whey protein from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; free histidine; and milk protein that has a level of 5% or more of amino acids as tryptophan, free tryptophan and mixtures thereof. Claim 20 recites a method of providing nutrition to an infant. The method includes administering a composition that includes whey protein wherein the whey protein is acid or sweet whey protein from which caseino-glyco-macropeptide has been removed; casein protein; free arginine; free histidine; milk protein that has a level of 5% or more of amino acids as tryptophan, free tryptophan or a mixture thereof.

According to the present invention, a composition for an infant formula and a method for its preparation are provided wherein the composition contains specific compounds which provide a balanced amount of all essential amino acids to an infant. Such compounds particularly include acid or sweet whey protein from which caseino-glyco-macropeptide (CGMP) has been

removed. This provides a composition with a reduced threonine and an increased tryptophan content which leads to a lower content of nitrogen in the compositions.

Applicants believe that the cited art is distinguishable from the claimed invention. The cited art provides a preparation of a nutritive composition which may be used as an infant food, particularly suitable for the treatment of some diseases. The composition includes whey powder, casein, different amino acids, lipids, carbohydrates, minerals and vitamins. See, XP-002158762, Abstract.

Nowhere does the cited art disclose or suggest to remove the CGMP from the whey protein in contrast to the claimed invention. Since this peptide subunit of the kappa-casein has a high threonine content but no aromatic amino acids, its removal leads to compositions that have a lower threonine content and a comparatively increased content of aromatic amino acids. This ensures that the composition has the required amino acids in sufficient amounts and also that the threonine content is reduced, where threonine represents the major source of nitrogen and generally yields an undesired overload with nitrogen. Again, the claimed compositions include acid or sweet whey protein from which caseino-glyco-macropeptide has been removed. This provides a reduced threonine and an increased tryptophan content and further can provide a balanced amount of all essential amino acids to an infant. Based on at least this reasons, Applicants believe that the cited art on its own fails to disclose or suggest the claimed invention and thus fails to render obvious same.

Accordingly, Applicants respectfully request that the obviousness rejection be withdrawn.

Applicants note for the record that it appears two references, namely European Patent Document Nos. 0418593A2 and 0880902A1, were not considered when submitted and identified in Applicants' previously submitted Information Disclosure Statement as evidence in the PTO Form 1449 that was provided along with the Office Action. At the outset, Applicants believe that the two European Patent Documents should have been entered on the record for examination purposes with respect to the present application. Indeed, in addition to copies of each of these patent documents, Applicants also submitted a copy of a PCT Search Report from a corresponding application that indicated the relevancy of each document.

However, in the spirit of cooperation, Applicants are submitting the European Patent Documents as discussed above again in a Supplemental Information Disclosure Statement along with English language abstracts for each of these patent documents. In addition, Applicants are also submitting in the Supplemental Information Disclosure Statement U.S. Patent No. 6,787,158 which is equivalent to the European Patent Document No. EP0880902. Moreover, Applicants respectfully refer the Patent Office to pages 4 and 5 of the Specification that include a description of the European Patent Document No. 0880902.

For the foregoing reasons, Applicants respectfully submit that the present application is condition for allowance and earnestly solicit reconsideration of the same.

Respectfully submitted,

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